

We Claim:

1. A catheter system having a disposable balloon, comprising:
 - (a) an elongated catheter comprising a first outer diameter, a first proximal end and a first distal end;
 - (b) an elongated balloon carrier having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrier and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrier, the second outer diameter of the balloon carrier being similar to the first outer diameter of the catheter; and
 - (c) a disposable balloon formed from an expandable and resilient biocompatible material, the balloon having a lumen disposed between a third proximal end and a third distal end thereof, the lumen having at least a third inside diameter, the second diameter of the carrier and the third diameter of the balloon being configured to permit the balloon first to be slideably mounted onto the balloon carrier and second to be slideably moved from the carrier onto the catheter when the second proximal end of the carrier is matingly engaged with the first distal end of the catheter.
2. The catheter system of claim 1, wherein the catheter is a PCA catheter.
3. The catheter system of claim 2, wherein a plurality of pressure transducers are mounted on the catheter at or between the first distal end and the first proximal end thereof.
4. The catheter system of claim 3, wherein the plurality of pressure transducers comprises a first pressure transducer mounted at or near the first distal end of the catheter and a second pressure transducer mounted on the catheter at a location proximal from the first pressure transducer.

5. The catheter system of claim 2, wherein the catheter further comprises a plurality of impedance measurement electrodes, the electrodes being mounted on the catheter at or between the first distal end and the first proximal end thereof.
6. The catheter system of claim 5, wherein the plurality of impedance measurement electrodes comprises two anodal ring electrodes and two cathodal ring electrodes.
7. The catheter system of claim 5, further comprising means for delivering high frequency alternating current between the electrodes.
8. The catheter system of claim 1, wherein the third inside diameter of the lumen engages the second outside diameter of the carrier near or at the proximal and distal ends of the balloon.
9. The catheter system of claim 8, wherein proximal and distal removable sleeves are disposed, respectively, between the third inside diameter of the proximal and distal ends of the lumen and the second outer diameter of the carrier.
10. The catheter system of claim 1, wherein the length between the proximal and distal ends of the balloon is selected from the group consisting of ranging between about 5 mm and about 100 mm, ranging between about 10 mm and about 80 mm, ranging between about 20 mm and about 60 mm, ranging between about 35 mm and about 55 mm, and ranging between about 40 mm and about 50 mm.
11. The catheter system of claim 1, wherein the balloon has a wall thickness selected from the group consisting of ranging between about 0.05 mm and about 1 mm, ranging between about 0.1 mm and about 0.5 mm, ranging between about 0.15 mm and about 0.35 mm, and ranging between about 0.2 mm and about 0.3 mm.
12. The catheter system of claim 1, wherein the third diameter is selected from the group consisting of ranging between about 3 mm and about 15 mm, ranging between about

4 mm and about 12 mm, ranging between about 5 mm and about 10 mm, and ranging between about 6 mm and about 9 mm.

13. The catheter system of claim 1, wherein the lumen further comprises a fourth inside diameter that is greater than the third inside diameter, at least portions of the lumen disposed near or at the third proximal end and the third distal end having the third inside diameter, at least portions of the lumen disposed between the third proximal end and the third distal end having the fourth inside diameter.

14. The catheter system of claim 1, wherein the fourth inside diameter is selected from the group consisting of between about 2 mm and about 20 mm, ranging between about 4 mm and about 15 mm, and ranging between about 6 mm and about 10 mm.

15. The catheter system of claim 1, wherein the catheter is a PCA catheter comprising means for introducing fluid into and withdrawing fluid from the balloon.

16. The catheter system of claim 1, wherein the balloon material, the third diameter of the balloon and the first diameter of the catheter are configured to sealingly engage the third inside diameters of the proximal and distal ends of the balloon against the first outside diameter of the balloon so as to prevent a fluid introduced inside the balloon from leaking outside the balloon.

17. The catheter system of claim 1, wherein the balloon comprises medical grade silicone.

18. The catheter system of claim 1, wherein the balloon comprises a material having a tensile strength selected from the group consisting of ranging between about 200 psi and about 3000 psi, and ranging between about 1000 psi and about 2000 psi.

19. The catheter system of claim 1, wherein the balloon comprises a material having a Shore durometer hardness selected from the group consisting of ranging between about 5 ShA and about 100 ShA, and ranging between about 30 ShA and about 70 ShA.

20. A disposable balloon for use in a catheter system comprising an elongated catheter having a first outer diameter, a first proximal end and a first distal end, an elongated balloon carrier having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrier and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrier, the second outer diameter of the balloon carrier being similar to the first outer diameter of the catheter, the balloon being formed from an expandable and resilient biocompatible material, the balloon comprising:

- (a) a lumen disposed between a third proximal end and a third distal end thereof, and
- (b) at least a third inside diameter;

wherein the second diameter of the carrier and the third diameter of the balloon are configured to permit the balloon first to be slideably mounted onto the balloon carrier and second to be slideably moved from the carrier onto the catheter when the second proximal end of the carrier is matingly engaged with the first distal end of the catheter.

21. The balloon of claim 20, wherein the third inside diameter of the lumen is configured to engage the second outside diameter of the carrier near or at the proximal and distal ends of the balloon.

22. The balloon of claim 20, further comprising proximal and distal removable sleeves for positioning, respectively, between the third inside diameter of the proximal and distal ends of the lumen and the second outer diameter of the carrier.

23. The balloon of claim 20, wherein the length between the proximal and distal ends of the balloon is selected from the group consisting of ranging between about 5 mm and about 100 mm, ranging between about 10 mm and about 80 mm, ranging between about

20 mm and about 60 mm, ranging between about 35 mm and about 55 mm, and ranging between about 40 mm and about 50 mm.

24. The balloon of claim 20, wherein the balloon has a wall thickness selected from the group consisting of ranging between about 0.05 mm and about 1 mm, ranging between about 0.1 mm and about 0.5 mm, ranging between about 0.15 mm and about 0.35 mm, and ranging between about 0.2 mm and about 0.3 mm.

25. The balloon of claim 20, wherein the third diameter is selected from the group consisting of ranging between about 3 mm and about 15 mm, ranging between about 4 mm and about 12 mm, ranging between about 5 mm and about 10 mm, and ranging between about 6 mm and about 9 mm.

26. The balloon of claim 20, wherein the lumen further comprises a fourth inside diameter that is greater than the third inside diameter, at least portions of the lumen disposed near or at the third proximal end and the third distal end having the third inside diameter, at least portions of the lumen disposed between the third proximal end and the third distal end having the fourth inside diameter.

27. The balloon of claim 20, wherein the fourth inside diameter is selected from the group consisting of between about 2 mm and about 20 mm, ranging between about 4 mm and about 15 mm, and ranging between about 6 mm and about 10 mm.

28. The balloon of claim 20, wherein the balloon comprises medical grade silicone.

29. The balloon of claim 20, wherein the balloon comprises a material having a tensile strength selected from the group consisting of ranging between about 200 psi and about 3000 psi, and ranging between about 1000 psi and about 2000 psi.

30. The balloon of claim 20, wherein the balloon comprises a material having a Shore durometer hardness selected from the group consisting of ranging between about 5 ShA and about 100 ShA, and ranging between about 30 ShA and about 70 ShA.

31. A method of making a disposable balloon for use in a catheter system comprising an elongated catheter having a first outer diameter, a first proximal end and a first distal end, an elongated balloon carrier having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrier and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrier, the second outer diameter of the balloon carrier being similar to the first outer diameter of the catheter, the balloon being formed from an expandable and resilient biocompatible material, the method comprising:

- (a) providing a mandrel having an outside surface defining a desired internal shape of the balloon;
- (b) providing a container having a biocompatible liquid silicone disposed therein;
- (c) dipping the mandrel in the liquid silicone to form a coated mandrel;
- (d) removing the coated mandrel from the liquid silicone;
- (e) heating the coated mandrel in an oven to form a heat cured balloon;
- (f) removing the mandrel and heat cured balloon from the oven; and
- (g) removing the heat cured balloon from the mandrel.

32. A disposable balloon system for use with an elongated catheter comprising a first outer diameter, a first proximal end and a first distal end, the disposable balloon system comprising:

- (a) an elongated balloon carrier having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrier and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrier, the second outer diameter of the balloon carrier being similar to the first outer diameter of the catheter; and
- (b) a disposable balloon formed from an expandable and resilient biocompatible material, the balloon having a lumen disposed between a third proximal end and a third

distal end thereof, the lumen having at least a third inside diameter, the second diameter of the carrier and the third diameter of the balloon being configured to permit the balloon first to be slideably mounted onto the balloon carrier and second to be slideably moved from the carrier onto the catheter when the second proximal end of the carrier is matingly engaged with the first distal end of the catheter.

33. The balloon system of claim 32, wherein the third inside diameter of the lumen is configured to engage the second outside diameter of the carrier near or at the proximal and distal ends of the balloon.

34. The balloon system of claim 32, further comprising proximal and distal removable sleeves for positioning, respectively, between the third inside diameter of the proximal and distal ends of the lumen and the second outer diameter of the carrier.

35. The balloon system of claim 32, wherein the length between the proximal and distal ends of the balloon is selected from the group consisting of ranging between about 5 mm and about 100 mm, ranging between about 10 mm and about 80 mm, ranging between about 20 mm and about 60 mm, ranging between about 35 mm and about 55 mm, and ranging between about 40 mm and about 50 mm.

36. The balloon system of claim 32, wherein the balloon has a wall thickness selected from the group consisting of ranging between about 0.05 mm and about 1 mm, ranging between about 0.1 mm and about 0.5 mm, ranging between about 0.15 mm and about 0.35 mm, and ranging between about 0.2 mm and about 0.3 mm.

37. The balloon system of claim 32, wherein the third diameter is selected from the group consisting of ranging between about 3 mm and about 15 mm, ranging between about 4 mm and about 12 mm, ranging between about 5 mm and about 10 mm, and ranging between about 6 mm and about 9 mm.

38. The balloon system of claim 32, wherein the lumen further comprises a fourth inside diameter that is greater than the third inside diameter, at least portions of the lumen disposed near or at the third proximal end and the third distal end having the third inside diameter, at least portions of the lumen disposed between the third proximal end and the third distal end having the fourth inside diameter.

39. The balloon system of claim 38, wherein the fourth inside diameter is selected from the group consisting of between about 2 mm and about 20 mm, ranging between about 4 mm and about 15 mm, and ranging between about 6 mm and about 10 mm.

40. The balloon system of claim 32, wherein the balloon comprises medical grade silicone.

41. The balloon system of claim 32, wherein the balloon comprises a material having a tensile strength selected from the group consisting of ranging between about 200 psi and about 3000 psi, and ranging between about 1000 psi and about 2000 psi.

42. The balloon system of claim 32, wherein the balloon comprises a material having a Shore durometer hardness selected from the group consisting of ranging between about 5 ShA and about 100 ShA, and ranging between about 30 ShA and about 70 ShA.

43. A catheter system having a disposable means for expanding, comprising:

- (a) an elongated catheter comprising a first outer diameter, a first proximal end and a first distal end;
- (b) an elongated means for carrying the expanding means having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrier and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrying means, the second outer diameter of the carrying means being similar to the first outer diameter of the catheter; and

(c) a disposable means for expanding formed from an expandable and resilient biocompatible material, the expanding means having a lumen disposed between a third proximal end and a third distal end thereof, the lumen having at least a third inside diameter, the second diameter of the carrying means and the third diameter of the expanding means being configured to permit the expanding means first to be slideably mounted onto the carrying means and second to be slideably moved from the carrying means onto the catheter when the second proximal end of the carrying means is matingly engaged with the first distal end of the catheter.

44. A disposable means for expanding for use in a catheter system comprising an elongated catheter having a first outer diameter, a first proximal end and a first distal end, an elongated means for carrying the expanding means having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrying means and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrying means, the second outer diameter of the carrying means being similar to the first outer diameter of the catheter, the expanding means being formed from an expandable and resilient biocompatible material, the expanding means comprising:

- (a) a lumen disposed between a third proximal end and a third distal end thereof, and
- (b) at least a third inside diameter;

wherein the second diameter of the carrying means and the third diameter of the expanding means are configured to permit the expanding means first to be slideably mounted onto the carrying means and second to be slideably moved from the carrying means onto the catheter when the second proximal end of the carrying means is matingly engaged with the first distal end of the catheter.

45. A disposable means for expanding system for use with an elongated catheter comprising a first outer diameter, a first proximal end and a first distal end, the disposable expanding means system comprising:

(a) an elongated means for carrying the expanding means having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrying means and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrying means, the second outer diameter of the carrying means being similar to the first outer diameter of the catheter; and

(b) a disposable means for expanding formed from an expandable and resilient biocompatible material, the expanding means having a lumen disposed between a third proximal end and a third distal end thereof, the lumen having at least a third inside diameter, the second diameter of the carrying means and the third diameter of the expanding means being configured to permit the expanding means first to be slideably mounted onto the carrying means and second to be slideably moved from the carrying means onto the catheter when the second proximal end of the carrying means is matingly engaged with the first distal end of the catheter.

46. A method of mounting a disposable balloon on an elongated catheter using a disposable balloon system, the elongated catheter comprising a first outer diameter, a first proximal end and a first distal end, the disposable balloon system comprising an elongated balloon carrier having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrier and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrier, the second outer diameter of the balloon carrier being similar to the first outer diameter of the catheter, and a disposable balloon formed from an expandable and resilient biocompatible material, the balloon having a lumen disposed between a third proximal end and a third distal end thereof, the lumen having at least a third inside diameter, the second diameter of the carrier and the third diameter of the balloon being configured to permit the balloon first to be slideably mounted onto the balloon carrier and second to be slideably moved from the carrier onto the catheter when the second proximal end of the carrier is matingly engaged with the first distal end of the catheter, the method comprising:

(a) providing the elongated catheter;

- (b) providing the disposable balloon system;
- (c) engaging the first distal end of the catheter against the second proximal end of the carrier, and
- (d) sliding the balloon onto the catheter from the carrier.

47. The method of claim 46, further comprising disposing proximal and distal sleeves beneath the proximal and distal ends of the balloon.

48. The method of claim 47, further comprising removing the sleeves after the balloon has been mounted on the catheter.